Supplemental Table 5. Serious Adverse Events

Participant	Description of event	Status	Outcome	Last injection before onset of AE	Date of AE onset	Study Group
1	Supraspinatous tendon tear	Received injections 1-4; Further injections discontinued prior to the event; Completed safety follow-up	Resolved following surgery and physical therapy	12/11/2002	2/25/2003	4-IM
2	Generalized allergic reaction	Received injections 1-6; Further injections discontinued; Did not complete safety follow-up	Resolved	09/01/2004	09/01/2004	5-IM
3	Bilateral pseudotumor cerebri with bilateral disc edema	Received injections 1-3; Further injections discontinued; Completed safety follow-up	Improvement noted following treatment	02/27/2004	04/13/2004	4-IM
4	New onset of generalized seizure; aqueductal stenosis	Received injections 1-6; Further injections discontinued; Completed safety follow-up	Maintaining without anti-seizure medication in September 2004	08/18/2004	09/27/2004	8-IM
5	Bilateral ductal carcinoma of the breast	Completed study prior to onset	No follow-up available	09/13/2006	1/3/2007	8-SQ
6	New onset bilateral arthralgia of the metacarpal joints; ANA positive[†]	Completed study prior to onset	No follow-up available	09/13/2006	1/22/2006	5-IM
7	Invasive ductal carcinoma of the breast	Received injections 1-6; Further injections discontinued; Completed safety follow-up	Following mastectomy and chemotherapy; in remission 18 months after diagnosis	09/14/2004	12/23/2004	SQ Placebo

[*]Blinded review using World Health Organization causality assessment criteria
[†]ANA=anti-nuclear antibody;